

Message Text

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62

ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-10 ISO-00 OES-05 /034 R

66617

DRAFTED BY: DHEW/FDA/JRWEINROTH, MD

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EUR/WE:WHMARSH (INFO)

EUR/IB:MDURKEE (INFO)

EA/PRCM:RHOLMES (INFO)

----- 030564

R 282221Z MAR 75

FM SECSTATE WASHDC

TO AMEMBASSY PARIS

AMEMBASSY MADRID

AMCONSUL HONG KONG

UNCLAS STATE 071108

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, FR, HK, SP

SUBJECT: FDAADVISORY - CONTAMINATED ANTI - RH TYPING SERUM,
(ANTI - E)

1. FDA ADVISES THAT THE PRODUCT ANTI - RH TYPING SERUM, ANTI - RH (ANTI - E), SLIDE AND RAPID TUBE TEST, MANUFACTURED BY SCHERING DIAGNOSTICS, SCHERING CORPORATION, PORT READING, NJ 07064 IN 2 ML AND 5 ML VIALS AND 1,000 ML BULK, LOT NUMBERS AS FOLLOWS: 720-1 (5 ML. VIALS), 721 (2 AND 5 ML. VIALS), 722 (1000 ML. BULK) ARE CONTAMINATED WITH A RARE GOA ANTI-BODY WHICH COULD LEAD TO FALSE TEST RESULTS.

2. FOREIGN CONSIGNEES AS FOLLOWS: LOT 720-1 (EXPIRATION DATE 6/12/75)- FOUR SHIPMENTS TO SPAIN WERE MADE TO DINTER, S.A. ENCARNACION 123, BARCELONA, 12, SPAIN. SHIPMENTS TO THIS CONSIGNEE INCLUDE INVOICE NUMBER 88173 20/5 ML. VIALS ON 6/21/74, INVOICE NO. 88327, 50/5 ML. VIALS ON 6/28/74, INVOICE NO. 89559, 30/5 ML. VIALS ON 11/6/74, INVOICE NO. 89559, 20/5 ML. VIALS ON 12/11/74.

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3. LOT 721 (EXPIRATION DATE 1/23/76 FOR 5 ML. VIALS, AND 11/8/75 FOR 2 ML. VIALS).

SHIPMENTS OF 40/5 ML. VIALS, INVOICE NO. 90102 WERE MADE TO DINTER, S.A. ENCARNACION 123, BARCELONA, 12, SPAIN.

2 ML. VIALS WERE SHIPPED TO HONG KONG PHARMACEUTICAL DISTRIBUTORS 45 HANKOW ROAD, SECOND FLOOR "H" TSIM SHA TSUI, KOWLOON, HONG KONG. SHIPMENTS TO THIS DISTRIBUTOR INCLUDE INVOICE NO. 90076 4/2 ML. VIALS ON 1/29/75, INVOICE NO. 89668, 2/2 ML. VIALS ON 11/21/74.

4. LOT 722 (EXPIRATION DATE 10/24/74). THIS ENTIRE LOT WAS SHIPPED IN 5/1000 ML. BULK CONTAINERS TO PRODUTEXA CO., 61 BOARDWAY, NEW YORK, NY. 1006 AND WAS SUBSEQUENTLY EXPORTED TO CENTRAL NATIONAL DE TRANSFUSION SANGUINE 6 RUE ALEXANDRE - CABANEL, PARIS XV, FRANCE.

5. POSTS ARE REQUESTED TO DETERMINE IF FOREIGN CONSIGNEES HAVE BEEN INFORMED BY SCHERING CORPORATION OF THE NATURE OF THE PROBLEM. KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: FOOD & DRUG REGULATIONS, IMMUNIZATION
Control Number: n/a
Copy: SINGLE
Draft Date: 28 MAR 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE071108
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH, MD
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750110-0129
From: STATE
Handling Restrictions: n/a
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ISecure: 1
Legacy Key: link1975/newtext/t1975035/aaaaaegc.tel
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Margaret P. Grafeld
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05 JUL 2006

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TAGS: OGEN, ETRD, TBIO, FR, HK, SP
To: PARIS HONG KONG
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006